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| 10/560,554 | 02/04/2006 | Jeroen Alphons Tonnaer | 2003-793US | 2808 |
| 67706 7590 12/08/2010 ORGANON USA, INC. c/o MERCK 2000 Galloping Hill Road Mail Stop: K-6-1, 1990 Kenilworth, NJ 07033 | | | | |
| EXAMINER KIM, JENNIFER M | | | | |
| ART UNIT 1628 | | PAPER NUMBER | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@spcorp.com

Office Action Summary

Application No.

10/560,554

Applicant(s)

TONNAER, JEROEN ALPHONS

Examiner

JENNIFER M. KIM

Art Unit

1628

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on July 29, 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-15 and 17-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-15 and 17-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI-108)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 29, 2010 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Delbressine et al. (U.S. Patent No. 5,763,476) of record.

Delbressine et al. teach that a composition comprising Org 5222 (also known as asenapine maleate) useful for the treatment of mental disorder such as schizophrenia. Delbressine et al. teach that the composition can be administered sublingually. (abstract, claims 1 and 4).

Applicant's recitation of treating schizophrenia without increasing body mass index (BMI) in a patient population is an inherent effect upon the administration of the same compound, asenapine, with the same amount via the same route of administration for the treatment of the same patient population having schizophrenia as disclosed by Delbressine et al.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Delbressine et al. (U.S. Patent No. 5,763,476) of record.

Delbressine et al. teach that a composition comprising Org 5222 (also known as asenapine maleate) useful for the treatment of mental disorder such as schizophrenia. Delbressine et al. teach that the composition can be administered sublingually. (abstract, claims 1 and 4).

Delbressine et al. do not teach the active agent in a kit with a label set forth in claim 7.

Claim 7 differs from the Delbressine et al. in that the claim recites the kit which contains a label for instructing that the contents can be used in the treatment of schizophrenia without increasing body mass index. Given that the Delbressine et al is for use by a human to treat schizophrenia, it would have been *prima facie* obvious to

one of ordinary skill in the art to include instructions as to how to administer the contents of the article for that purpose. The instructions would differ from those recited in claim 7 only in the wording of the instructions including the content which does not increase the body mass index. However, it is noted that the printed matter such as label in the instructions has no functional relation with the substrate on which it appears, it does not distinguish Applicants' claimed invention over that of Delbressine et al. *See In re Gulack*, 703 F.2d1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983). Hence, the article in a kit recited in claim 7 would have been *prima facie* obvious to one of ordinary skill in the art over Delbressine et al.

Claims 4, 8-12, 15 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Delbressine et al. (U.S.Patent No. 5,763,476) of record in view of Aronne (2001) and further in view of Alexander-Bridges et al. (U.S.Patent No. 5,496,831).

Delbressine et al. teach that a composition comprising Org 5222 (also known as asenapine maleate) useful for the treatment of mental disorder such as schizophrenia. Delbressine et al. teach that the composition can be administered sublingually. (abstract, claims 1 and 4).

Delbressine et al. do not teach that the schizophrenic patients population disclosed by Delbressine et al. having BMI values set forth in claims 4, 10 and 11 and the population is in need of protection against weight gain.

Aronne teaches that the rate of patients with schizophrenia comorbid with obesity is higher compared to the general population (abstract). Aronne teaches the term "overweight" is defined as having a body mass index (BMI) of ≥ 25 (page 13 left-hand column first full paragraph).

Alexander-Bridges et al. teach that obesity can be measured by determining the body mass index (BMI) which is the ratio of the weight (kg) to the square of the height (m) of the subject. The treatment to decrease body fat is generally recommended for women with a BMI of above 27, and men with a BMI above 28. (column 5, lines 55-66).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ Org 5222 (also known as asenapine maleate) to schizophrenic patients comorbid with obesity having a body mass index (BMI) of ≥ 25 . One would have been motivated to make such a modification because in general, there is high rate of a patient with schizophrenia comorbid with obesity that is known to be defined as a patient having a BMI of ≥ 25 as taught by Aronne, and because Delbressine et al. teach that asenapine is useful for the treatment of schizophrenia in general. One would make such a modification in order to achieve a beneficial effect of asenapine in treatment of schizophrenia inclusive of those comorbid with obesity with the patient having a body mass of ≥ 25 . There is a reasonable expectation of success in treatment of schizophrenia in a patient with overweight problems like obesity because the effectiveness of asenapine in treatment of schizophrenia would be retained regardless of their weight. With regard to schizophrenic patient population in need of protection against weight gain, such is obvious because the patient population having

schizophrenia are generally comorbid with obesity as taught by Aronne et al. Therefore, the schizophrenic patients are generally in need of protection against weight gain.

With regard to schizophrenic patient population treated having BMI values set forth in claims 4, 10 and 11, such are obvious because Aronne teaches that patient who are over weight is defined as having BMI greater than or equal to 25 and Alexander-Bridges et al. further teach that treatment to decrease body fat is generally recommended for women with a BMI of above 27, and men with a BMI above 28 as well known. There is a lack of teaching in the specification that the BMI value in the applicants' population is critical.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Response to Arguments

Applicant's arguments filed July 29, 2010 have been fully considered but they are not persuasive. Applicant argues that none of the cited publications describe or suggest that asenapine is useful in the treatment of schizophrenia without increasing BMI in a patient population. This is not persuasive because Delbressine et al. teach that a composition comprising Org 5222 (also known as asenapine maleate) useful for the

treatment of mental disorder such as schizophrenia. Delbressine et al. teach that the composition can be administered sublingually. Therefore, Applicant's recitation of treating schizophrenia without increasing body mass index (BMI) in a patient population is an inherent effect upon the administration of the same compound, asenapine, with the same amount via the same route of administration for the treatment of the same patient population having schizophrenia as disclosed by Delbressine et al. Applicant's argue that the examiner's conclusion of obviousness is based upon improper hindsight reasoning. This is not persuasive because it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In this case, at the time the invention was made Applicant's instantly claimed subject matter of treating schizophrenia with the active agent, asenapine was fully taught by Delbressine et al. The limitation of without increasing body mass index (BMI) in a patient population during the same pharmacological treatment of schizophrenia is an inherent effect upon the administration of the same compound, asenapine, with the same amount via the same route of administration for the treatment of the same patient population having schizophrenia as disclosed by Delbressine et al. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER M. KIM whose telephone number is (571)272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JENNIFER M KIM/
Primary Examiner, Art Unit 1628

Jmk
December 1, 2010